510(k) SUMMARY

MAR - 8 2010

Submitter:

Draeger Medical Systems, Inc.
6 Tech Drive
Andover, MA 01810-2434

Contact Person:

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Date submission was prepared: December 4, 2009

Device Name:

Trade Name:	Infinity® Acute Care System™ (IACS) Monitoring Solution
Common Name:	Physiological Patient Monitoring Solution
Classification Name:	Monitor, Physiological, Patient (with arrhythmia detection or Alarms)
Product Code:	MHX
Class:	II
Regulation Number:	21 CFR 870.1025

Legally Marketed Device: Infinity Alpha

Infinity Explorer

Device Description:

The Infinity® Acute Care System™ (IACS) Monitoring Solution is a multi-parameter physiological patient monitoring system that acquires and displays patient data at the bedside and in transport within the hospital setting. The IACS Monitoring Solution is a combination of two devices; Infinity M540 patient monitor with Infinity M500 docking station; and Infinity C500 software with Infinity C500 Medical Cockpit. Infinity C700 software with C700 Medical Cockpit is an option for a larger screen.

The Infinity M540 patient monitor is a light weight hand held portable patient monitor that displays real-time vital signs and provides continuous trending. The Infinity M540 patient monitor is capable of monitoring Heart rate, Arrhythmia (adult and pediatric only), 12-lead monitoring, ST segment analysis including TruST (adult and pediatric only),12-lead ST segment analysis (adult and pediatric only), Apnea, Respiration rate, Invasive pressure, Non-invasive pressure, Temperature, Cardiac output, Arterial oxygen saturation, Pulse rate (SpO2), and Mainstream etCO2. The device produces visual and audible alarms if any of the physiological parameters monitored vary beyond preset limits and timed or alarm recordings will be produced. The Infinity M540 patient monitor can be used as a stand alone medical device without any integration with the Infinity C500 Medical Cockpit.

The Infinity C500 software allows the user to extend the viewing capability of the Infinity M540 patient monitor and integrates additional patient information on Infinity C500 Medical Cockpit. The Infinity C500 Medical Cockpit is a medical grade display monitor with limited monitoring control features. The Infinity C500 software is capable of displaying real-time patient data, providing control back to the Infinity M540 and integrating other applications with patient data on the Infinity C500 Medical Cockpit.

Intended Use: The Infinity® Acute Care System™ (IACS) Monitoring Solution:

The IACS is intended for multi-parameter, physiologic patient monitoring of adult, pediatric, and neonatal patients in environments where patient care is provided by trained healthcare professionals. The IACS obtains the physiologic, multi-parameter data from the connection to the M540 monitor and optional medical devices and displays. The transfer of this data is accomplished by the Infinity network.

Intended Use: Infinity M540 Patient Monitor

The Infinity M540 is intended for the monitoring of multi-parameter, physiological patient information obtained from connected hardware in environments where patient care is provided by trained healthcare professionals. The M540 is intended to monitor one patient at a time.

Indications for Use:

The M540 monitors the following parameters:
- Heart rate
- Arrhythmia (adult and pediatric only)
- 12-lead analysis
- ST segment analysis including TruST® (adult and pediatric only)
- 12-lead ST segment analysis (adult and pediatric only)
- Apnea
- Respiration rate
- Invasive pressure
- Non-invasive pressure

– Temperature
– Cardiac output
– Arterial oxygen saturation
– Pulse rate (SpO2)
– Mainstream etCO2

MRI Compatibility Statement:

The IACS, Infinity M540 and any connected optional hardware are not intended for use in hyperbaric chambers and environments containing MRI equipment

Predicate Devices:

- Infinity Alpha with software VA0 K051658
- Infinity Kappa and Delta Series Monitors with VF7 modifications K070566
- Infinity Explorer with VF6 modifications and MDS III display K060254

Substantial Equivalence:

Assessment of non-clinical performance data for equivalence:
The Infinity Acute Care System (IACS) Monitoring Solution has been tested in accordance with applicable standards and internal design control procedures and was determined to be as safe and effective for its intended use as the predicate device(s).

Assessment of clinical performance data for equivalence:
Clinical performance evaluations indicate that the Infinity Acute Care System (IACS) Monitoring Solution is substantially equivalent to the Infinity Alpha patient monitor and Infinity Explorer with MDS III display.

Biocompatibility:

Not applicable - The Infinity Acute Care System (IACS) Monitoring Solution and its components do not directly contact with the patient. If patient contact is made, it is transient and with the intact unbroken skin.

Sterilization:

Not applicable - The Infinity Acute Care System (IACS) Monitoring Solution and its components are not supplied sterile.

Standards and Guidance:

Electrical Safety: IEC 60601-1: Medical electrical equipment general requirements for safety and essential performance; and applicable and collateral standards

Guidance Documents: "Deciding When to Submit a 510(k) for a Change to an Existing Device" released on January 10, 1997 "Format for traditional and Abbreviated 510(k)s" issued on August 12, 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR - 8 2010

Mr. Bryan Cowell, RAC
Senior Regulatory Compliance Specialist
Draeger Medical Systems, Inc.
6 Tech Drive
Andover, MA 01810-2434

Re: K093788
Device Name: Infinity® Acute Care System™ (IACS) Monitoring Solution
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with Arrhythmia Detection or Alarms)
Regulatory Class: Class II (Two)
Product Code: MHX
Dated: December 4, 2009
Received: December 9, 2009

Dear Mr. Cowell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

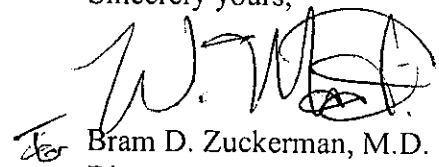
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093788

Device Name: Infinity® Acute Care System™ (IACS) Monitoring Solution

Intended Use: The Infinity® Acute Care System™ (IACS) Monitoring Solution:

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- Invasive pressure
- Non-invasive pressure
- Temperature
- Cardiac output
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- Pulse rate (SpO2)
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Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093788